

REMARKS

Claims 1-6, 8-64 and 73-75 are pending in the application. Claims 65-72 stand withdrawn from consideration. Reconsideration is respectfully requested in view of the above comments and the following remarks.

Applicants thank Examiner for the courtesies extended during the telephonic interview with the undersigned and applicant Dr. Paul Zupkas on May 18, 2004. The substance of the interview has been set forth by Examiner in a continuation sheet (PTOL-413), to the Interview Summary.

In response to Examiner's remarks in the Interview Summary Record, claims 1, 33 and 39 have been amended to replace the word "sized" with "*adapted*". Claim 14 has been amended to replace "sized" with "*is adapted*".

Claims 1-4, 8-11, 13-15, 18-23, 32-36, 39-42, 44-50, 58, 61 and 64 stand rejected as allegedly anticipated by D'Augustine *et al.*

D'Augustine Fig. 6 discloses a transvaginal delivery system comprising a proximal tampon portion (45) for absorbing discharge from the uterus, specifically menstrual blood, and a distal porous foam portion (43) containing medication for delivery to the vagina and uterus. The porous foam portion (43) is described as fabricated from "a soft, light weight, physiologically inert foam material of polyurethane, polyester, polyether, ...or collagen...."(col. 15, lines 13-16). The porous foam portion (43) provides a housing for the medication which after insertion is released and delivered to the cervical tissue. After drug delivery, the porous foam portion (43), along with the tampon portion (45), is removed. Both have the same shape and structure as prior to insertion. A tube (44) extends between the foam portion and the distal end portion of the absorbent tampon and is centrally located to convey blood flow to the absorbent tampon. A proximal end (46) of the blood flow tube includes a plastic loop (47) for receiving a string (48) to provide for removal of an inserted tampon device.

The claimed invention is directed to a urethral suppository, not a vaginal tampon as described by D'Augustine. The preamble language "urethral suppository" gives "life and meaning" to the claim, and therefore serves as a limitation. *See Corning Glass Works v.*

Sumitomo Elec. U.S.A., Inc., 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). Where, as here, the claim preamble is part of the definition of the invention, it constitutes a claim limitation. See *Diversitech Corp. v. Century Steps, Inc.*, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988).

A “suppository” is “[a] small solid body shaped for ready introduction into one of the orifices of the body other than the oral cavity (e.g., rectum, urethra, vagina), made of a substance, usually medicated, which is solid at ordinary temperature but melts at body temperature”. *PDR Medical Dictionary*, 1st ed., Medical Economics, Montvale, New Jersey, 1995, p. 1706 (copy enclosed). The vaginal device of D’Augustine Fig. 6 is not a urethral suppository. The body of the D’Augustine vaginal device is not meltable but is principally composed of materials which do not melt. The materials disclosed for the porous foam portion (43) are polyurethane, polyester, polyether and collagen. These materials are not meltable at body temperature. The *absorbent tampon* (45) part of the D’Augustine Fig. 6 device is also not meltable. A “tampon” is “[a] cylinder or ball of cotton-wool, gauze or other loose substance; used as a plug or pack in a canal or cavity to restrain hemorrhage, absorb secretions, or maintain a displaced organ in position”. *PDR Medical Dictionary* p. 1761 (copy enclosed). Designed to form an obstruction against discharge of blood or other secretions, a tampon can not be meltable at body temperature, since it would fail for its intended purpose. A tampon must remain intact to perform its blockage function.

The present invention is a urethral suppository comprising a base member, reinforcing member, and meltable portion. The meltable portion contains the medication. Consistent with the dictionary definition of “suppository”, the meltable portion is inserted as a solid and melts as it reaches body temperature. This means the urethral suppository of the invention will be inserted with the shape and structure of the meltable portion surrounding the reinforcing member. The meltable portion will then melt as it reaches body temperature until the meltable portion is completely gone. The device is then removed with the shape and structure of the reinforcing member only. In contrast, the shape and structure of the D’Augustine device is not effected by the process of insertion and removal. Hence, it is clear that the D’Augustine Fig. 6 device is not a urethral suppository, and does not anticipate claim 1 or 33.

Claims 1 and 33 are not anticipated by D'Augustine Fig. 6 for other reasons. The claims recite a non-meltable base member attached to a non-meltable reinforcement which projects from the base member. The base member is adapted to prevent its insertion into the urethra. Thus, the base member serves as a stop for limiting the insertion of the suppository into the urethra. Examiner alleges that the D'Augustine plastic loop (47) the non-meltable base member feature of the claimed invention. It is respectfully submitted that Examiner is incorrect.

Tube (44) to which the loop (47) is connected is embedded entirely in the porous foam portion (43) and tampon portion (45) of the D'Augustine device. The primary function of the tube (44), is a conduit for blood, while the loop (47) serves merely as an attachment point for a removal string (See col. 15, line 20). The loop (47) is not a base member. A "base" is defined in *Webster's Collegiate Dictionary*, G. & C. Merriam Company, Springfield, MA, 1977, p. 92 (copy enclosed) as "the bottom of something considered as its support".

Located in the interior of the D'Augustine device, loop (47) does not function as a base for the Fig. 6 device, and cannot function to limit the insertion of the device into any body channel, let alone a urethra. Loop (47) is buried in the center of the tampon (45) portion of the device and can not contact any body surfaces. Loop (47) merely serves as an attachment structure for string (48), which is used to withdraw the tampon device from the vagina. Masked by the surrounding absorbent material of tampon (45), cannot interact with any body structure to limit the insertion of the device into a body channel. Loop (47) is not adapted to prevent insertion into the urethra. It is in fact easily inserted in the vagina with the other portions of the D'Augustine device. Considering the size of the loop with respect to the size of the surrounding tampon, it is expected that loop would have a diameter of about 1/10th the diameter of a typical vaginal tampon. Even assuming *arguendo* that the loop could be utilized in an intraurethral device (which is not suggested by D'Augustine), it would not be prevent from entering the urethra.

Reconsideration and withdrawal of the anticipation rejection of claims 1 and 33 is respectfully requested.

Claims 2-4, 8-11, 13-15, 18-23, 32, 34-36, 39-42, 44-50, 58 recite additional features of the claimed urethral suppository. Claims 61 and 64 recite a method of using the claimed suppository. These claims are likewise free of the anticipation rejection.

Claim 24, 25, 31, 51, 52, 62, 63 and 73-75 stand rejected as being allegedly obvious over D'Augustine. These claims recite specific ranges of dimensions or durations of use with respect to the urethral suppository of claim 1 or 33. Examiner alleges that it would have been obvious to form the meltable portion of the claimed device with dimensions as claimed, to accommodate the vagina of patients of various sizes. As indicated above, the claimed invention is a urethral suppository, not a vaginal tampon. Accommodating different vagina sizes has nothing to do with the configuration of a urethral suppository, which is designed for insertion into a different body canal. The tampon of D'Augustine is not for insertion into the urethra. Thus, D'Augustine provides no guidance for dimensioning a device for insertion into the urethra.

The claims of the application are believed to be in condition for allowance. An early action toward that end is earnestly solicited.

Respectfully submitted,
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